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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/486,293	08/22/2000	JONATHAN A COOPER	14538A-004010US	3432

7590 08/10/2006

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EXAMINER

GEBREYESUS, KAGNEW H

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/486,293

Applicant(s)

COOPER ET AL.

Examiner

Kagnew H. Gebreyesus

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-8 and 10-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,6-8 and 10-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
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| <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/08/2000</u>.</p> | <p>4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>7/25/06 & 7/26/06</u>.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 30, 2006 has been entered.

Priority

Acknowledgment for priority is made for the instant application which claims the benefit of U.S. Provisional Serial No. 60/056,473, filed August 21, 1997.

Information Disclosure Statement

The information disclosure statement filed on December 8, 2000 for which a copy of the patent, publications was submitted in this application will be reviewed in full.

Oath/Declaration

The oath or declaration submitted with the response to missing documents on pages 66-67 of the 87 page letter on August 22, 2000 has been reviewed and is in compliance with 37 CFR 1.63.

Applicant's arguments filed on June 30, 2006 in response to the Office action mailed on December 29, 2005 are acknowledged. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Status of Claims

Claims 1, 6, 10-13 have been amended. Claims 3-5, 9 and 17-35 have been cancelled. Claims 1-3, 5-8, 10-18 are pending. Claims 1, 2, 6-8, 10-16 are present for examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are rejected because of the recitation "...a complementary sequence thereof..." Does this term comprise any fragment of any size that are complementary to any region in the nucleic acid encoding SEQ ID NO: 3? It is suggested that applicants amend this claim to recite "...the complementary sequence thereof..." However for examination purposes the broadest interpretation of the claim will be considered. Therefore the claim will be read as encompassing any nucleic acid sequence of any size that is complementary to the polynucleotide that encodes SEQ ID NO: 3.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 6-16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification describes a DNA sequence that encodes the polypeptide of SEQ ID NO: 3, which inherently comprise the fully complementary sequence. However the specification does not describe any sequence of any size that comprises a sequence complementary to the sequence encoding SEQ ID NO: 3. Said sequences could range between a few nucleotides that are common to a large number of DNA sequences to sequences that are larger than the full-length sequence. Thus claims 1, 2, 6-16 as claimed would not lead a skilled artisan to conclude that applicants were in possession of all the claimed species. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Furthermore Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, because claims 6-8 recite "a probe" which comprises an oligonucleotide capable of hybridizing at a specific hybridization condition and wash conditions at a temperature of 5-25°C below the T_m ..." without specifying the structure of any oligonucleotide sequence. In addition claim 7 recites a probe

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comprising 15-60 nucleotides. Thus these claims are defined by physicochemical characteristics and are directed to a genus of oligonucleotide probes of any size (given that claim 7 is drawn to a probe *comprising* 15-60 undefined nucleotides). However the specification does not describe the structure of any probe, which is capable of hybridizing to the specific sequence encoding SEQ ID NO: 3 at a specific hybridization condition. In addition the specification does not describe the structure of any probe wherein the T_m can be measured in view of determining the wash conditions which require a high temperature of 5 to 25 C below the T_m . Given this lack of description encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

Claims 6-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 6-8 do not describe the structure of any probe thus a skilled artisan would not know how to determine the T_m of such a probe which is a requirement for the functional characterization of the claimed probe(s). The specification, teaches on page 10 line 36-38 and page 11 line 1 and 2 oligonucleotides of 15 or more nucleotides of SEQ ID NO: 2, 4 or 6 and complementary strands thereof capable of hybridizing under stringent conditions to isolated and purified polynucleotide molecules encoding mDab1. Thus while one can determine the T_m for a probe comprising any oligonucleotide sequence having 15 or more contiguous nucleotides derived from SEQ ID NO:

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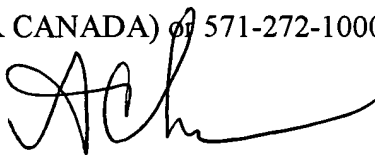
2, 4 or 6 and use such determination to adjust the temperature for the wash conditions required after the hybridization step, one of skill in the art would not know how to determine the wash temperature required for any probe for which the structure has not been disclosed. Thus claims 6-8 do not fulfill the enablement requirement because the claims contain subject matter (structural disclosure) not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnev H. Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy Ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kagnev Gebreyesus PhD.



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